

AMENDMENTS TO THE CLAIMS:

This listing of claims will replace all prior versions, and listings, of claims in the application:

LISTING OF CLAIMS:

Claims 1 to 29 (Canceled).

Claim 30 (Original) A pharmaceutically acceptable starch, especially for parenteral administration, preferably by way of injection, to a mammal, especially a human, which

- a) has an amylopectin content in excess of 85 percent by weight, in which the molecular weight of said amylopectin has been reduced, preferably by shearing so that at least 80 percent by weight of the material lies within the range of 10-10,000 kDa,
- b) has a purity of at most 50 μ g amino acid nitrogen per gram dry weight of starch, preferably at most 20 μ g, more preferably at most 10 μ g, and most preferably at most 5 μ g, amino acid nitrogen per gram dry weight of starch,
- c) can be dissolved in a concentration exceeding 25 percent by weight in water.

Claim 31 (Original) A pharmaceutically acceptable starch, especially for parenteral administration, preferably by way of injection, to a mammal, especially a human, which

- a) has an amylopectin content in excess of 85 percent by weight, in which the molecular weight of said amylopectin has been reduced, preferably by shearing so that at least 80 percent by weight of the material lies within the range of 10-10000 kDa,
- b) has a purity of at most 50 μg amino acid nitrogen per gram dry weight of starch, preferably at most 20 μg amino acid nitrogen, more preferably at most 10 μg , and most preferably at most 5 μg amino acid nitrogen per gram dry weight of starch,
- c) lacks covalently bonded additional chemical groups of the type that occur in hydroxyethyl starch.

Claim 32 (Currently amended) A starch according to ~~any one of claims 30 and 31~~
claim 30 which exhibits the ability to gel in vitro.

Claim 33 (Original) A starch according to claim 31, which exhibits the ability to form microparticles in an emulsion system, especially a two-phase aqueous system.

Claim 34 (Original) A starch according to claim 31, which has an endotoxin content of less than 25 EU/g and contains fewer than 100 microorganisms per gram.

Claim 35 (Canceled).

Claim 36 (Original) A starch according to claim 31 in which said molecular weight of the amylopectin is within the range of 100-4000 kDa, preferably 200-1000 kDa and more preferably 300-600 kDa.

Claim 37 (Original) A starch according to claim 31 which can be dissolved in water in a concentration exceeding 30%, preferably exceeding 40%, and more preferably exceeding 45%, by weight.

Claim 38 (Original) A starch according to claim 31, which remains in solution at a temperature of at most 60°C, preferably 20-45°C, especially 30-37°C, for a period sufficiently long to allow combining with a substance that is temperature sensitive and/or unstable in organic solvents, especially a protein.

Claim 39 (Original) A starch according to claim 38, wherein said combining is performed at conditions which are able to retain the bioactivity of said substance.

Claim 40 (Original) A starch according to claim 31, which when dissolved in water solidifies at a temperature of 1-55°C, especially 4-37°C.

Claim 41 (Original) A starch according to claim 40, which solidifies when exposed to an initial temperature of 1-10°C, especially about 4°C, and subsequently to a temperature of 20-55°C, preferably 25-40°C, especially about 37°C.

Claim 42 (Original) Microparticles based on starch as a carrier for a biologically active substance, especially for parenteral administration, preferably by way of injection, to a mammal, especially a human, in which said starch is the starch as defined in claim 31.

Claim 43 (Original) Microparticles according to claim 42, which have a mean particle diameter in the range of 10-200 µm, preferably 20-100 µm, especially 20-80 µm.

Claim 44 (Currently amended) Microparticles according to ~~any one of~~ claim 42, which exhibit the ability to be dissolved by enzymatic action in vitro or eliminated from biological tissue in vivo.

Claim 45 (Currently amended) Microparticles according to ~~any one of~~ claim 42, in which the biologically active substance is a protein.

Claim 46 (New) A starch according to claim 31 which exhibits the ability to gel in vitro.

Claim 47 (New) A starch having a purity of at most 50 μg amino acid nitrogen per gram dry weight of starch and an endotoxin content of less than 25 EU/g and containing fewer than 100 microorganisms per gram, said starch being pharmaceutically acceptable for injection into a human being and obtainable by a process starting from starch in solid form with an amylopectin content in excess of 85 percent by weight expressed as dry weight of starch comprising the following steps:

- (a) subjecting said solid starch to washing(s) under conditions such that proteins, lipids and endotoxins surface-localized on the starch as well as more sparingly soluble proteins are dissolved while the starch remains undissolved, and separating the starch from the dissolved material, said washings comprising a washing with an aqueous alkaline solution for dissolving said water-soluble proteins, lipids and endotoxins and a washing with an aqueous solvent with the ability to dissolve zein for dissolving said more sparingly soluble proteins,
- (b) causing the washed starch obtained from step (a) to dissolve in an aqueous medium,
- (c) subjecting the starch solution to a molecular weight reduction by shearing such that a molecular weight distribution is obtained in which at least 80 percent by weight of the material lies within the range of 10-10000 kDa; and
- (d) removing residual water-soluble proteins from the starch by subjecting the starch solution to ion exchange chromatography, said ion exchange chromatography being performed either before or after the shearing step (c) wherein the starch is pharmaceutically acceptable for injection into a human being.